REMARKS

Applicants respectfully requests reconsideration of the present application in view of the foregoing amendments and the following commentary.

I. Status of the Claims

Claims 4, 36, 38, 40, 42, 53, and 83 are cancelled without prejudice or disclaimer thereof. Claims 1, 46, and 76 have been amended to essentially incorporate the recitations of claims 4, 53 and 83, respectively. Accordingly, claims 5-7, 54-56, and 84-86 have been amended to correct the dependency. Claims 69 and 103 have been amended to replace the trademarks with their corresponding generic terms. Claims 70 and 104 have been amended for greater clarity.

Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 1-3, 5-35, 37, 39, 41, and 43-45 are under examination, with claims 46-52, 54-82, and 84-123 withdrawn from consideration.

Applicants appreciate the Examiner's indication that claim 7 is allowable.

Because the Examiner required restriction between product and process claims and Applicants elected product claims for initial examination, Examiner is respectfully reminded that the process claims should be rejoined for consideration upon allowance of the product claims.

II. Rejection of Claims under 35 U.S.C. §112, first paragraph

Claims 36, 38, 40, 42, 44 and 45 are rejected under 35 U.S.C. §112, first paragraph, for alleged lack of enablement. Applicants respectfully traverse the rejection.

Without acquiescing to the stated basis for the rejection, Applicants choose to advance the prosecution by cancelling claims 36, 38, 40 and 42, thereby mooting the rejection of these claims.

At page 9 of the Office Action, first paragraph, the Examiner clarified that "the issue here [the rejection under 35 U.S.C. §112, first paragraph] does not lie in the definition of the term 'bioequivalent'..." Because claims 44 and 45 are directed to compositions, wherein "bioequivalency" of each composition is specifically defined, the rejection lacks valid basis and should be withdrawn.

III. Rejection of Claims under 35 U.S.C. §102(b)

Claims 1-3, 8-10, 12, 14-15, 17, 21-24, 26-30 and 32-45 are rejected under 35 U.S.C. §102(b) for alleged anticipation by U.S. Patent No. 5,665,331 to Bagchi et al. ("Bagchi"). Applicants respectfully traverse the rejection.

Bagchi teaches a composition comprising a crystal growth modifier that is at least 75% structurally identical to the drug (abstract; column 4, lines 15-22; column 10, lines 54-56). In contrast, the claimed composition comprises at least one osmotically active crystal growth inhibitor, such as glycerol, propylene glycol, mannitol, sucrose, glucose, fructose, mannose, lactose, xylitol, sorbitol, trehalose, a polysaccharide, a mono-polysaccharide, a di-polysaccharides, a sugars, a sugar alcohol, sodium chloride, potassium chloride, magnesium chloride, and an ionic salt. Clearly, the crystal growth inhibitors of the claimed invention are distinguishable from the crystal growth modifier of Bagchi. Therefore, Bagchi fails to teach each and every aspect to anticipate the claimed invention. Withdrawal of the rejection is respectfully requested.

IV. Rejection of Claims under 35 U.S.C. §103(a)

A. Liversidge 1 and Straub

Claims 1-4, 6, 8-24, 26-30 and 32-45 are rejected under 35 U.S.C. §103(a) for alleged obviousness over U.S. Patent No. 6,267,989 to Liversidge ("Liversidge 1"), in view of U.S.

Patent Application Publication No. 2002/0142050 by Straub et al. ("Straub"). Applicants respectfully traverse the rejection.

As pointed out by the Examiner, Liversidge 1 solves the issue of crystal growth and aggregation in nanoparticulate compositions without using any crystal growth inhibitor. As such, one skilled in the art would have had no reason to incorporate a crystal growth inhibitor taught by Straub into the compositions of Liversidge 1 to prevent crystal growth.

B. Liversidge 1, Straub and Liversidge 2

Claims 25 and 30-45 are rejected under 35 U.S.C. §103(a) for alleged obviousness over Liversidge 1, in view of Straub and U.S. Patent Application Publication No. 2005/0004049 by Liversidge ("Liversidge 2"). Applicants respectfully traverse the rejection.

Liversidge 1 and Straub are discussed *supra*. The Examiner cited Liversidge 2 for the alleged teaching of the active agents suitable in a bioadhesive composition. Claims 25 and 30-45, all depending from a non-obvious base claim, are also non-obvious for the same reasons.

C. Bagchi, De Garavilla and Straub

Claims 1-6, 8-10, 12, 14-15, 17, 21-24, 26-30 and 32-45 are rejected under 35 U.S.C. §103(a) for alleged obviousness over Bagchi, in view of U.S. Patent No. 5,834,025 to De Garavilla et al. ("De Garavilla") and Straub. Applicants respectfully traverse the rejection.

Bagchi describes its crystal growth modifiers at column 10, lines 49-60. By Bagchi's definition, a crystal growth modifier must posses at least 75% identity in chemical structure to the active agent. Exemplary crystal growth modifiers are listed at column 11. The Examiner suggested use of glycerol and mannitol in the claimed composition based on the teachings of De Garavilla and Straub.

One skilled in the art would have had no reason to substitute Bagchi's crystal growth modifier for either glycerol or mannitol. This is because glycerol and mannitol do not posses the requisite 75% chemical identity to the active agent. Thus, the Examiner's suggested combination would be inapposite to the express teaching of suitable crystal growth modifiers in Bagchi and would not be suitable for the intended purpose of Bagchi.

In view of the foregoing, Applicants respectfully request withdrawal of all rejections under 35 U.S.C. §103(a).

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 3 July 2008

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